

Comirnaty (COVID-19 Vaccine, mRNA)

What data did FDA evaluate to support the September 11, 2023, approval of a single dose of Comirnaty for individuals 12 years of age and older?

The effectiveness of a single dose of Comirnaty for individuals 12 years of age and older, regardless of prior COVID-19 vaccination status, is supported by FDA's previous determination of the effectiveness of Comirnaty and analysis of immune response data from a clinical study among approximately 260 individuals 18 through 85 years of age who were COVID-19 unvaccinated and had evidence of prior SARS-CoV-2 infection. These individuals received a single dose of an investigational bivalent Pfizer-BioNTech COVID-19 vaccine, and their immune responses were compared to the immune responses of approximately 270 participants without evidence of prior SARS-CoV-2 infection who received two doses of Comirnaty (Original monovalent), one month apart. The immune response data demonstrated that individuals who had prior evidence of infection responded adequately to a single dose of vaccine.

The safety of a single dose of Comirnaty for individuals 12 years of age and older, regardless of prior COVID-19 vaccination status, is supported by FDA's previous determination of the safety of Comirnaty and data from a clinical study among approximately 700 individuals 12 years of age and older who received a second booster dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA4.BA.5). The most commonly reported side effects were pain at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The data accrued with the authorized and investigational bivalent Pfizer-BioNTech COVID-19 vaccines are relevant to Comirnaty because all of these vaccines have a similar manufacturing process.